

Serial No.: 10/539,952

Confirmation No.: 8655

Filed: March 6, 2006

For: DENTAL MATERIAL CONTAINING BACTERIOSTATIC AND/OR BACTERICIDAL SUBSTANCES

Remarks

The Office Action dated March 29, 2010 has been received and reviewed. Claims 17 and 28-32 having been amended, claims 1-16 having been previously cancelled, claim 27 having been cancelled herein, without prejudice, and no claims having been added, the pending claims are claims 17-26 and 28-34. Reconsideration and withdrawal of the rejections are respectfully requested.

Support for the amendment to claim 17, 31, and 32 may be found throughout Applicants' specification and specifically in, for example, claims 27 and 28. Claims 28-30 have been amended to provide appropriate antecedent basis and to remove "typical."

Entry and consideration of the claim amendments are requested.

The 35 U.S.C. §102 Rejections

The Examiner rejected claims 17-26 under 35 U.S.C. §102(a) as being anticipated by Wagner et al. (WO 2002/006820). The Examiner rejected claims 17-20, 22, and 23 under 35 U.S.C. §102(b) as being anticipated by Bowen (U.S. Pat. No. 5,603,921). The Examiner rejected claims 17-20, 22, 23, and 28-30 under 35 U.S.C. §102(b) as being anticipated by Pflug et al. (WO 98/48766). Applicants traverse the rejections.

Applicants maintain that the claims provided in the Amendment and Response dated October 23, 2009 are patentable for at least the reasons provided in Applicants' Remarks therein at pages 10-15. However, without acquiescing to the Examiner's rejection and merely to expedite the prosecution of the present application, claim 17 has been amended to incorporate the subject matter of claim 27 and some aspects of claim 28. For at least the reason that claim 27 was not subject to any anticipation rejection, the present anticipation rejections must fail.

Reconsideration and withdrawal of the anticipation rejections based on Wagner et al., Bowen, and Pflug et al. are requested.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 27 and 33-34 under 35 U.S.C. §103(a) as being unpatentable over Pflug et al. (WO 98/48766) in view of Geistlich et al. (U.S. Pat. No. 4,096,241). Claim 27 has been cancelled, rendering moot the rejection thereof. Insofar as the rejection may apply to the present claims, Applicants traverse the rejection.

Amended claim 17 recites a dental material including a polymerizable component, an initiator and/or an accelerator and/or a retarding agent; and at least one substance whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms; wherein the at least one substance comprises taurolidine. Amended claim 33 recites a dental material including a polymerizable component, an initiator for the polymerizable component, and taurolidine. Claim 34 recites a dental material including taurolidine and wherein the dental material is a dental filling material, a glass ionomer cement, a temporary dental filling material, or a dental impression material.

Applicants submit that the Examiner has not established a *prima facie* case of obviousness of independent claims 17, 33, and 34 over Pflug et al. in view of Geistlich et al. for at least the reason that one of skill in the art would not have been motivated based on the cited documents to make a combination as proposed by the Examiner and would not have had a reasonable expectation of success in doing so.

The Examiner admitted that Pflug et al. fail to disclose taurolidine. Thus, the Examiner relied upon Geistlich et al. for the disclosure of taurolidine and alleged that it would have been obvious to use Geistlich et al.'s taurolidine in the dental materials of Pflug et al. The Examiner alleged that the motivation to make such a combination is maintaining antimicrobial properties known to have low toxicity over long periods of time.

It is submitted that combining Pflug et al. and Geistlich et al. is not obvious. Geistlich et al. disclose oral care compositions, but not those with curable or hardenable compositions (e.g., "polymerizable component" in claims 17, 33, and 34).

One of skill in the art would not have had a reasonable expectation of success. For example, one of skill in the art would not have expected that the curable compositions of Pflug et

al. would still be curable and that the curing mechanism would not be negatively affected by the addition of Geistlich et al.'s taurolidine. Moreover, one of skill in the art would not have expected that taurolidine would still be effective when added to the curable compositions of Pflug et al.

It may not be necessarily concluded that if one takes a substance (e.g., taurolidine) that has been used in non-curable compositions (e.g., mouthwashes, dentrifices, etc.), then that substance can also be used in curable compositions. When a substance is put into a curable composition, the substance will typically remain within the composition, especially if the composition is cured. Thus, it would be expected that the efficacy of the substance would be dramatically reduced (e.g., as compared to the substance in a liquid composition, such as mouthwash).

Surprisingly, Applicants found that a substance (e.g., taurolidine) whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms may be incorporated into a curable composition. Moreover, the structure of Geistlich et al.'s taurolidine is very much different from that of Pflug et al.'s triclosan and, thus, it may be assumed that the mechanism used by triclosan to kill germs may be different from that used by taurolidine.

Further, Pflug et al. describe triclosan as being "soluble in many organic solvents [and] stable to hydrolysis" (page 4, lines 3-5). In contrast, Geistlich et al. describe taurolidine as a formaldehyde carrier (column 1, lines 28-29) and, thus, is not stable to hydrolysis. If the Examiner needs evidence of this, it can be provided upon request.

Pflug et al. disclose that low water solubility is advantageous: "As the water solubility of triclosan is low and it is embedded in a crosslinked polymer matrix, leaching of the triclosan is low, resulting in a long-term antimicrobial effect." (Page 6, lines 1-4, emphasis added; *see also* page 7, lines 16-21.) Thus, Pflug et al. effectively teach away from the use of taurolidine, which is water soluble. If the Examiner needs evidence of this, it can be provided upon request. Further, in contrast, Geistlich et al. disclose use of taurolidine in toothpastes, tooth gels, and mouth washes (column 2, lines 28-32), not embedded in a polymeric matrix.

Applicants submit that one of skill in the art would not be motivated to use taurolidine, which is not stable to hydrolysis and is water soluble, in the dental material of Pflug et al., to replace triclosan, which is stable to hydrolysis and has low water solubility.

The Examiner, in simply stating that it would have been obvious to exchange Pflug et al.'s triclosan with Geistlich et al.'s taurolidine, has not provided adequate and proper reasoning sufficient to establish a *prima facie* case of obviousness. Once the solution to a problem is known, one can be tempted to import hindsight and allege it is obvious. Thus, Applicants respectfully submit that the Examiner's combination of Pflug et al. in view of Geistlich et al. must have been as a result of improper hindsight analysis.

As reasserted in *Princeton Biochems., Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332; 75 USPQ2d (BNA) 1051 (Fed. Cir. 2005), 35 U.S.C. §103 specifically requires an assessment of the claimed invention "as a whole." This "as a whole" assessment of the invention requires a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the various elements from the cited references and combined them in the claimed manner. In other words, 35 U.S.C. §103 requires some suggestion or motivation, before the invention itself, to make the new combination. See *In re Rouffet*, 149 F.3d at 1350.

In *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727; 167 L.Ed.2d 705; 82 USPQ2d (BNA) 1385 (2007), the U.S. Supreme Court has acknowledged the utility of this "teaching, suggestion, motivation" inquiry when determining the obviousness of an invention by recognizing that the inquiry arose from "helpful insight" of the Court of Customs and Patent Appeals. The inquiry arose as a guard against a finding of obviousness where an examiner or a court was able to find all of the elements of an invention in the prior art, but without any suggestion or motivation to combine the prior art references that described the elements in question. The Court reiterated that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." 167 L.Ed.2d at 14.

This "as a whole" instruction in 35 U.S.C. §103 prevents evaluation of the invention part by part, aided by the template of Applicants' disclosure. Without this important requirement, an

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obviousness assessment might reduce an invention into its component parts, then find a reference corresponding to each component. This type of assessment would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. The U.S. Supreme Court cautioned against such analysis in *KSR*, stating, “A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.” (167 L.Ed.2d at 725, citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), warning against a “temptation to read into the prior art the teachings of the invention in issue” and instructing courts to “guard against slipping into the use of hindsight” (383 U.S. at 36, quoting *Monroe Auto Equipment Co. v. Heckthorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (6th Cir. 1964))).

For at least the reasons provided herein, the Examiner has failed to establish a *prima facie* case of obviousness of claims 17, 33, and 34. Applicants respectfully request reconsideration and withdrawal of the obviousness rejection based on Pflug et al. in view of Geistlich et al..

Request for Rejoinder

Withdrawn claims 31 and 32 recite subject matter that is similar to that of, for example, independent claim 17. Upon an indication of claim 17 being allowable, Applicants respectfully request that claims 31 and 32 be rejoined and examined pursuant to M.P.E.P. §821.04, which states that “[t]he propriety of a restriction requirement should be reconsidered when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder.”

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Summary

It is respectfully submitted that all of the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop AF, P.O. Box 1450, Alexandria, VA 22313-1450, on this 1st day of June 2010.

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